DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 24, 2014

Codent Technical Industry Company Limited
Chin-Ting Wen
Specialist
5F., No. 90, Luke 5th Road, Luzhu District
Southern Taiwan Science Park
Kaohsiung City 82151
TAIWAN

Re: K133069
Trade/Device Name: Codent Low Speed Dental Handpieces and Accessories
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: I
Product Code: EFB, EGS
Dated: September 19, 2014
Received: September 22, 2014

Dear Mr. Wen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133069

Device Name: Codent Low Speed Dental Handpieces and Accessories

Indications for Use:

The Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Prescription Use ___X___ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

1. Type of Submission: Traditional

2. Revised Date: 2013/12/31

3. Submitter:

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5F., No.90, Luke 5th Rd., Luzhu Dist., Kaohsiung City 821, Taiwan (R.O.C.)

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Contact: Chin-Ting Wen / Specialist

Establishment Registration Number: 3004082152

4. Identification of the Device:

Proprietary/Trade name: Codent Low Speed Dental Handpieces and Accessories

Common Name: Air-Powered Dental Handpieces & Contra- And Right-Angle Attachment

Classification Name: Dental Handpiece & Accessories

Device Classification: 1

Regulation Number: 872.4200

Panel: Dental

Product Code: EFB/EGS

5. Identification of the Predicate Device:

Predicate Device Name: A-dec/W&H Synea Air-Driven Highspeed Handpiece, Models TA-98, TA-97
A-dec/W&H Synea Handpiece Attachment, Models WA-99LT, WA-86LT, WA-66LT, WA-56LT, HA-43LT

Manufacturer: A-DEC, INC.

510(k) Number: K070663

Predicate Device Name: Premium Slow Speed Dental Handpieces and Accessories

Manufacturer: Sable Industries, Inc.

510(k) Number: K083101

6. Intended Use and Indications for Use of the subject device.

Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

7. Device Description

Codent Low Speed Dental Handpieces and Accessories include low speed air motor, straight handpiece and contra-angle handpiece. The Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

The gear ratios of handpieces are 1:5 and 1:1, with the maximum speed of 200,000 rpm and 40,000 rpm. AI4C and AI2N air motors can be connected to LAISAI, LBIPA1, LEIPD4 and LEIPC4 hanpieces. AE4N and AE2N air motors can be connected to LAESA2 and LDEPA2 hanpieces. The 4 air motors are capable of running up to a speed of 25,000 rpm.

8. Non-clinical Testing

The tests listed below were conducted for Codent Low Speed Dental Handpieces and Accessories in accordance with the following standards.

- ISO 7785-2:1995 Dental Handpiece — Part 2: straight & Geared Angle Handpieces
- ISO 13294:1997 Dental Handpiece — Dental Air Motors
- ISO 3964:1982 Dental Handpieces — Coupling Dimensions
- ISO 1797-1: 2011Dentistry — Shanks for Rotary Instruments - Part 1: Shanks Made of Metals
- ISO 14971:2007 Medical devices — Application of risk management to medical devices
- ISO 9168:2009 Dentistry - Hose connectors for air driven dental handpieces
- ANSI/AAMI ST79:2010/A3:2012 — Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Amendment 3
- ISO 14457:2012 Dentistry — Handpieces and Motors
- Guidance for Industry and FDA Staff-Dental Handpieces-Premarket Notification [510(k)] Submissions
- ISO 10993-1:2009, Biological Evaluation of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process

All the test results demonstrate the performance of Codent Low Speed Dental Handpieces and Accessories meets the requirements of its pre-defined acceptance criteria and intended uses. Conformity with the above standards also demonstrates that the Codent Low Speed Dental Handpieces and Accessories are as safe and effective as the predicate devices.

9. Substantial Equivalence Determination

The Codent Low Speed Dental Handpieces and Accessories submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the devices cleared in K070663 and K083101. In the chart below, the entire intended use for all predicate devices are listed, but it should be noted that the proposed device has SE with A-dec/W&H Synea Handpiece Attachment (not A-dec/W&H Synea Air-Driven Highspeed Handpiece, models TA-98, TA-97) and Premium Slow Speed Dental Handpieces and Accessories.

Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Intended Use	
Proposed Device	The Codent Low Speed Dental Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.
Predicate Device (K083101)	Sable Industries Premium Slow Speed Dental & Accessories are indicated for use in general dentistry for cleaning and polishing of teeth.
Predicate Device (K070663)	The A-dec/W&H Synea Air-Driven Highspeed Handpiece is an air-powered dental handpiece for use in general dentistry. This device is designed for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. The A-dec/W&H Synea Handpiece Attachment is powered by either an air-motor or electric micromotor for use in general dentistry. This device is designed for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth.
Models	
Proposed Device	LAISA1, LBIPA1, AI4C, AI2N, LAESA2, LDEPA2, AE4N, AE2N, LEIPD4, LEIPC4
Predicate Device (K083101)	p/n 1610101, p/n 1610801, p/n 1610801, p/n 1600411, p/n 1600508, p/n 1610299, p/n 1610201, p/n 1610301

Predicate Device (K070663)	WA-99LT, WA-86LT, WA-66LT, WA-56LT, HA-43LT
Standards	
Proposed Device	ISO 7785-2:1995 , ISO 13294:1997 , ISO 3964:1982 , ISO 1797-1: 2011 ,ISO 9168:2009, ISO 14971:2007, ANSI/AAMI ST79:2010/A3:2012, ISO 14457:2012, ISO 10993-1:2009
Predicate Device (K083101)	ISO 13294, ISO 7785-2, ISO 9168, ISO 17665-1, ISO 11134, ISO 10993-1
Predicate Device (K070663)	Unknown

More comparative items are listed in Section of Equivalence Discussion.

10. Conclusion

After analyzing bench tests and safety testing data, it can be concluded that Codent Low Speed Dental Handpieces and Accessoriesis substantially equivalent to the predicate devices.